***Remarks/Arguments*:**

Claims 6-11, submitted hereby, are pending in the application.

Claims 1-5 are canceled hereby, without prejudice or disclaimer.

Claims 6-11 correspond to amended versions of claims 6-11, respectively, of record in parent application no. 09/890,277, which were under final rejection.

Present claim 6 represents claim 6 in the parent with the language "an amorphous state at" deleted. Present claims 8 and 11 correspond to claims 8 and 11 in the parent amended to recite that the a "dose" of the spray is administered "wherein the ubiquinone Q-10 is present in an amount of 20-1000 my dose, as described in the specification at page 2, second complete paragraph.

Present claims 7, 9, and 10 correspond to claims 7, 9, and 10 in the parent, as dependent on present claim 6.

Claims 6-11 in the parent were subject to final rejection under 35 USC 112, paragraph 2, and under 35 USC 112, first paragraph. Both §112 rejections were based on the language "in an amorphous state." Neither §112 rejection is applicable against present claims 6-11, since the presnt claims do not recite "in an amorphous state."

However, the term "ubiquinone Q10 in an amorphous state" constitutes neither indefinite language nor new matter. The expression is taken from the reference WO 95/05164. There is no technical difference between the term "amorphous state" and "colloidal dispersion".

Claims 6 and 7 in the parent were rejected (final) under 35 USC 102(b) for allegedly being anticipated by Westesen (WO 95/05164). The rejection is not applicable against present claims 6

and 7, or any of the present claims.

Westesen discloses particles in an amorphous state (i.e, colloidal particles in a dispersion medium). The statement of rejection is correct that the reference discloses administration by oral or nasal application; but, Westesen does not disclose or suggest administration in the form of a spray. For example, nasal administration could be effected by a creme or a gel and oral administration could be in the form of a tablet, a capsule, a beverage, or the like. Therefore, claims 6 and 7 are not anticipated, by Westesen.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products*, Inc., 225 USPQ 253 (Fed. Cir. 1985). The absence from a prior art reference of a single claim limitation negates anticipation. *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81 (Fed. Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "identically appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir.1997) *(emphasis added)*. To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

In the present situation, the claim feature (limitation) administration in the form of a "spray" of ubiquinone Q-10 is absent from Westesen. As such, anticipation based on Westesen is negated, *Kolster Speedsteel A B, supra*, and the rejection is, thus, not applicable against the present calims.

To the extent the rejection relied on a "spray" being inherently described in Westesen, the reliance was (and would be) misplaced. For the doctrine of inherency to apply it must be

"inevitable" from the teachings of the prior art. *In re Wilding*, 190 USPQ 59, 62 (CCPA 1976) (*emphasis added*). "In relying on a theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (*emphasis in original*). Before "the burden shifts," the examiner has "the initial burden of establishing a prima facie basis for the alleged inherency." 17 USPQ2d at 1463-64. To base a rejection on what is allegedly inherent in the reference teachings,

> the examiner must ... reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the applied prior art.

17 USPQ2d at 1464 (*emphasis in original*).

As explained, above, oral and nasal administration as taught in Westesen can be accomplished by means other than a spray. Therefore, use of a "spay," as in the rejected and present claims, is not an *inevitable* feature of Westesen. Accordingly, anticipation of neither the rejected claims, nor the present claims, is shown based on Westesen, *Wilding, supra*, and, so, the reference can not be relied on to make the rejection under §102(b).

Claims 6-11 were rejected under 35 USC 103(a) as allegedly obvious based on Nyce (U.S. Patent No. 5,660,835) and under 35 USC 103(a) as allegedly having been obvious based on the combined teachings of Westesen and Matthews (*Proc.Natl.Acad.Sci.*, 95, 8892-97 (1998). The rejections under §103(a) would not apply against present claims 6-11.

As explained above, Westesen discloses neither a spray nor, as correctly set forth in the

statement of rejection, therapeutic application recited in claims 8 to 11. In contrast to the statement of rejection, however, this deficiency is not overcome by Matthews.

According to Matthews oral administration of coenzyme Q10 increases both brain and brain mitochondrial concentrations of Q10. The reference teaches that Co-Q-10 is protective against the toxic substance 3-nitopropionic acid and it might be useful in the treatment of neurodegenerative diseases. The amount of Q10 used in Matthews is 200 mg/kg per day. For a 75 kg human, this would correspond to 15 g per day.

As explained on page 2, second complete paragraph, of the present specification, doses of about 20 mg are sufficient. By the instant Amendment, claims 8 and 11 are limited to treatment by spraying a "dose", the amount of Co-Q-10 in the dose being "20 to 1000 mg."

Although, Matthews discloses protection against systemic administration of 3-nitropropionic acid, the reference does not disclose treatment of pain conditions from neural disorders, migraine, neuropathy, depressions, psychoses, lack of concentration, Alzheimer's, Parkinson's, Huntington's, multiple sclerosis, or cerebral palsy.

Moreover, as disclosed in the instant specification, page 2, second complete paragraph, treatment with about 20 mg in the form of a spray is more effective than treatment with 800 mg of Q10 in the form of a capsule. This surprising effect could not have been expected in view of the prior art.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior

art." *In re Wilson* , 165 USPQ 494, 496 (CCPA 1970). A "ground of rejection is simply inadequate on its face ... [when] the cited reference do not support each limitation to [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002). When conducting an obviousness analysis, "all limitations of a claim must be considered in determining the claimed subject matter as is referred to in 35 U.S.C. 103 and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982). An argument by the PTO is "not prior art." *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). When the

> PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears *in the reference*. ... The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient to establish inherency. ... [S]uch a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.

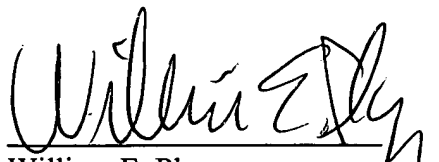
28 USPQ2d at 1557 (*emphasis added*).

Matthews adds nothing that cures the fatal deficiency of Westesen as a §102(b) reference, as explained above. Accordingly, since all limitations in the present claims are neither taught nor suggested by Westesen in view of Matthews, a case of *prima facie* obviousness of the present claims based on Westesen in view of Matthews would not apply. *Royka, supra.*

Favorable action is requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By 

William E. Player
Reg. No. 31,409

400 Seventh Street, NW
The Jenifer Building
Washington, D.C. 20004
Tel. (202) 638-6666
Fax (202) 393-5350
Date: December 22, 2003
WEP/bap
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